nubeca

POE101B, C Fingertip Pulse Oximeter

User Manual

Ver 1.0 March, 2013

SYMBOL INFORMATION

EC REP	Authorized representative EU
	Separate collection for electrical and electronic devices (WEEE)
CE	CE Marking
	Read instructions before use
	Do not use if package is damaged
SN	Serial number
IPX2	Resistant to liquid ingress
	Type BF, not defibrillator proof
	Caution; consult accompanying documents

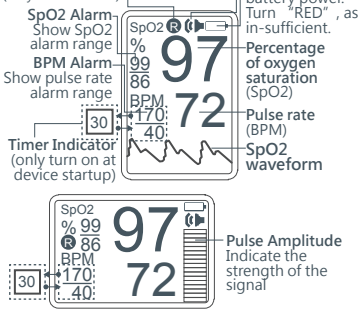
CONTENTS OF PACKAGE

POE101 includes the following items:

A. Fingertip Pulse Oximeter, 1 unit
B. User Manual, 1 sheet
C. Quick reference card, , 1 piece
D. Warranty Card, 1 piece
E. AAA-Size Alkaline Battery, 1 piece
F. USB cable, 1 piece (for POE101B only)

Please make sure all items are packed. All items are non-sterile. If any item missing or damaged, contact your distributor.

DISPLAY INTERFACE



CAUTION!

- This oximeter is not an apnea monitor.
- Significant levels of dysfunctional hemoglobin such as carbonxyhemoglobin or methemoglobin may affect the accuracy of the measurement.
- Cardio green and intravascular dyes may affect the accuracy of **POE101**.
- The performance of the oximeter might be affected by the presence of a defibrillator.
- The oximeter may not work on all subjects. If you are unable to achieve stable readings, please discontinue use.
- The oximeter has motion tolerant algorism to minimize the possible motion artifact. However, the oximeter may be still interpreted by motion. Please minimize subject motion as much as possible.
- All the materials of the oximeter in contact with a patient or a user have passed ISO10993 Biological evaluation of medical devices accordingly. It shall be no toxicity harm to children, pregnant or nursing women.

INTENDED USE

POE101 is intended for measuring functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate for both adults and children as non-invasive spot checking and continuous monitoring in home and professional caring environment, and transport and mobile environment. It is designed for fingers between 0.8cm and 2.3cm (0.3 inch ~ 0.9 inch) and for patients during no-motion condition.

PRINCIPLE OF OPERATION

▶physiological Principle

POE101 determines SpO_2 by measuring the absorption of red & infrared light passing through perfused tissue. Changes in absorption caused by the pulsation of blood in the vascular bed are used to determine SpO_2 reading and pulse rate.

▶Data Update and Signal Processing

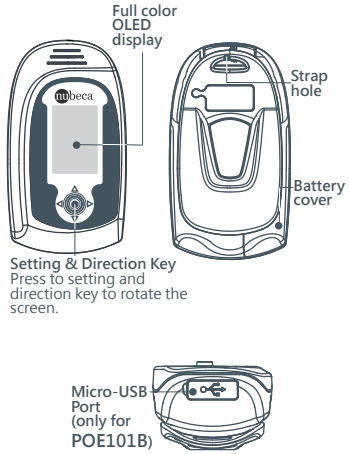
POE101 in the algorithms automatically extends the amount of data required for measuring SpO_2 and pulse rate depending on the measuring conditions. During normal measurement conditions, the averaging time is three to six heart beats. POE101 automatically adjusts the signal processing during degraded conditions, such as low perfusion, ambient light, electromagnetic interference, and patient motion, which results in an increase in the dynamic averaging beyond 10 heart beats or may reach 40 heart beats.

- **Pulse Amplitude Indicator**
  The Pulse Amplitude Indicator indicates pulse beat and shows the relative (non-normalized) pulse amplitude. As the detected pulse becomes stronger, the bar will go higher with each pulse.
- **SpO_2 Waveform Display**
  Similarly, when a waveform is selected, the display provides the (non -normalized) real-time sensor signal. The relative pulsatile strength and quality of the incoming signal can be observed.

WARNINGS

- Do not use the oximeter in an MRI or CT environment.
- The oximeter is intended as an adjunct in subject assessment. It must be used in conjugation with other methods to assess clinical signs and symptoms.
- Do not use the oximeter in an explosive atmosphere to avoid explosion hazard.
- If the monitoring sites have trauma, disability or other medical conditions, users should consult doctors before use.
- The oximeter has to measure the pulse properly to obtain accurate SpO_2 reading. Blood flow restrictors (e.g., blood pressure cuffs) may hinder pulse measurements. Remove any objects that may hinder the performance of the oximeter.
- Please do not leave the device to a child and always keep the battery cover in attach to avoid swallowing by a child.
- Federal law (USA) restricts this device to sale by or on the order of a physician.

DEVICE FEATURES


Full color OLED display
Strap hole
Battery cover
Setting & Direction Key
Press to setting and direction key to rotate the screen.
Micro-USB Port (only for POE101B)

BEFORE USE

▶First Time Use

For the first time use, a protective plastic membrane is attached to the front panel of the oximeter. Please remove the plastic membrane to allow the OLED display to show its best performance.

▶Battery Replacement

Before start any measurement, please make sure the battery power is sufficient and the setting is correct. If not, please refer to the following procedures.
Make sure the oximeter is off when replacing the battery. The device is powered by one AAA-size alkaline battery. Please press the ▯▯▯▯▷ mark on the battery cover to open it up and installing a new battery.

CAUTION!

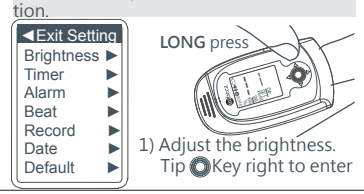
Please dispose the battery according the proper procedure.

▶Setup the Device

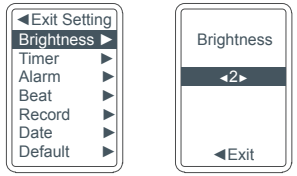
The device allows user to setup the 1) OLED brightness, 2)initial timer option, 3) SpO_2 & pulse rate alarm range, 4) audio reminder, 5) data recording interval, 6) date & time and 7) factory default by **LONG** pressing the ◉ key. The setting mode can be entered either when the device is off or under operation.

CAUTION!

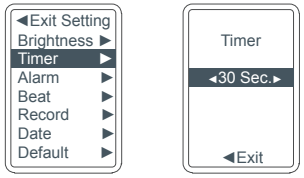
Tip ◉Key right to enter a sub-menu. For exit, tip it left at "Exit" selection. Under adjustment menu, tip ◉Key right or left to increase or decrease value, or change selection and press down for confirmation.



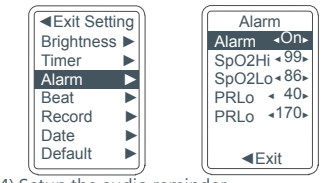
1) Adjust the brightness.
Tip ◉Key right to enter the sub-menu, please select among level 1~4 to adjust OLED brightness. Level 4 is the brightest and level 1 is the lowest. Please select higher level for high ambient light environment and lower level for power conservation. press down for confirmation.



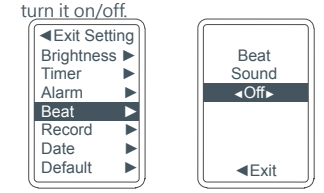
2) Setup the initial timer.
The oximeter provides a simple timing mechanism at the beginning of each measurement. For this feature, users can set the timing period to be 30 seconds, 1 minute, or turn it off.



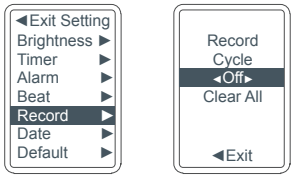
3) Setup SpO_2 and pulse rate alarm range
POE101B,C provide alarm option for abnormal SpO_2 and pulse rate reading. Users can select the different SpO_2 high, SpO_2 low, pulse rate (PR) high and pulse rate low limit to trig the alarm or turn it off under this submenu. Please refer to "SPECIFICATION" table for allowable setting range of the different parameters. The alarm range will be shown next to the measurement on the display, when the alarm option is turned on.



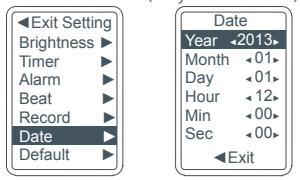
4) Setup the audio reminder.
The oximeter can give a audio pulse sound. Please use this submenu to turn it on/off.



5) Setup the data recording interval (only for POE101B).
The oximeter can record the SpO_2 and pulse rate. Users can set the recording interval as 30 seconds, 1 minute, 5 minutes or turn it off. The corresponding time will be from 24 hours to 10 days. For delete all the memory, please select "Clear All" for it.

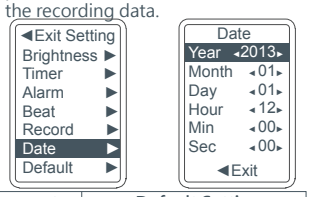


6) Set date and time (only for POE101B).



The date and time will be collect with each measurement. Please make sure it is correct, before recording.

7) Back to factory default setting
The option takes all of the setting, except date&time, back to the factory default. It only resets the parameters and does not be erased the recording data.



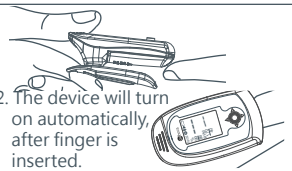
Parameter	Default Setting
Brightness	Level 2
Timer	Off
Alarm	SpO2 Hi off; SpO2 Lo 87% PR Hi off; PR Lo off
Beat sound	On
Record	Off

⚠ CAUTION!

1. **POE101** can be operated by either a patient or a trained personnel. Consult healthcare professionals before use.
2. The oximeter might not work on cold extremities due to poor circulation. Please warm or rub the finger , or reposition the device to improve it.
3. Check the applied site of a patient frequently to evaluate body circulation and skin sensitivity. The recommended maximum applied time at a single spot is 4 hours. Misapplication of the oximeter on applied site with excessive pressure for prolonged periods can introduce pressure injury.

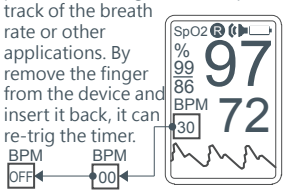
OPERATION

STEP1. Open up the oximeter and put one of your fingers into the opening. Please make sure that your finger face up and touch the bottom of the opening before releasing the clamp.



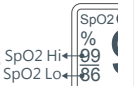
STEP2. The device will turn on automatically, after finger is inserted.

STEP3. If timer indicator option is on, it will start to count down right away. The time left will be showed in the square beneath BMP. When time is up, "OFF" will be showed. This feature can serve as timer for patients or care givers to keep track of the breath rate or other applications. By remove the finger from the device and insert it back, it can re-trig the timer.

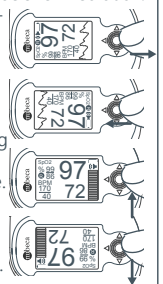


STEP4. After detecting the pulse signal, the oximeter shows SpO2 and pulse rate on the display. The readings will be updated based on the signal received with each pulse. If is on, the beat sound will be generated.

STEP5. If the alarm option is on, the SpO2 and pulse rate (PR) alarm range will be showed on the left side beside the SpO2 and pulse rate reading. Normally, alarm condition delay is less than 7 heart beats for SpO2; and less than 6 heart beats for pulse rate, after oximetry condition is altered in the finger. For alarm signal generation delay, it is less than 100 milliseconds for both SpO2 and pulse rate. If the function is completed turned off, the icons will not be showned at all.



STEP5. During the operation, if you tip key up, down, left, or right,the screen will rotate in its direction to allow users viewing the results in desired view angle.



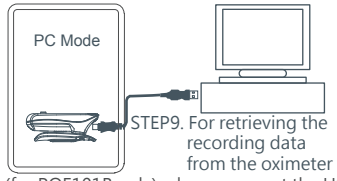
STEP6. Press the Key on top and the device will enter the setting mode.

⚠ CAUTION!

If the device experiences a data or alarm condition update period exceeding 30 seconds, the display will shows RED "00" for both SpO2 and pulse rate reading.

STEP7. If the finger is not detected or removed, the oximeter will show " FingerOut" . As the finger keeps to be undetectable, the device will turn off automatically in about 3 seconds.

STEP8. If the data recording option is on (for POE101B only) will be showed on the display and the SpO2 and pulse rate measurement with corresponding date and time in a preset interval will be recorded within the oximeter.



STEP9. For retrieving the recording data from the oximeter (for POE101B only), please connect the USB cable within the package from the micro-USB port of POE101B to a computer. The oximeter will then show "PC mode" . At this moment, POE101B will act only as data storage device and has no more oximetry function. After the USB cable is pull out, the device will turn off and its oximetry function will be restored . (Please consult with your local distributor for its download instruction.)

⚠ CAUTION!

For electrical safety and data downloading quality, please only use the USB cable enclosed within POE101B package.

MAINTENANCE AND STORAGE

- Remove the batteries inside the battery compartment if the oximeter will not be operated for more than one month.
- It is best to preserve the product in a place where ambient temperature range is from -30ºC to 70ºC (-22ºF to 158ºF), humidity range from 15% to 90%, and atmospheric pressure range from 700 hPa to 1013 hPa.
- The commercially available bench top functional testers and patient simulators may only be suitable to validate the pulse rate, but may not be able to verify the proper oximetry of this pulse oximeter. Please consultant with your distributor or the manufacturer proper model and the usage of functional testers and patient simulators for this oximeter. Furthermore, the testers and simulators may be useful for verifying that the pulse oximeter being incapable of providing the data required to properly evaluate the accuracy of a system's SpO2 measurements.

TROUBLESHOOTING

Problem	Possible Causes	Solutions
The oximeter won't turn on.	The battery is dead.	Replace with a new battery.
	The battery is installed incorrectly.	Verify correct battery orientations.
	Finger might be trembling or place incorrectly.	Keep the finger steady or align the finger inward at veritcal-middle of the device.
Display lockup or blank. If the device is on a finger, changes will appear at wave form or pulse amplitude bar.	OLED displays is malfunction.	The reading might not be reliable; discontinue using the device.
	Electromagnetic interference (EMI).	Remove the surrounding electronic devices away.
	Finger might be trembling or place incorrectly.	Keep the finger steady or align the finger inward at veritcal-middle of the device.
No reading of SpO2 or pulse rate and shows dash-line.	Low finger pulse quality.	If it shows less than 2 amplitude bars, please try the following. 1. Reposition the finger. 2. Warm the finger by rubbing. 3. Select another finger.
SpO2 or pulse rate alarm appears	A patient's condition is abnormal.	Provide immediately mdeical attention to this patient.
Date & time or initial timer is not correct.	The internal ±0.004% variation from timming circuit.	Enter the setting mode and setup to correct date & time.
	Timing circuit is malfunction.	Replace with a new battery.
Unable to enter the setting mode.	The battery power is low. The key might be malfunction.	Try to restart the device through reinstall the battery.
Low battery "" appears on display	The battery power is low.	Replace with a new battery.

If you have followed the actions recommended above but the problem keeps unresolved, please call you agent for assistance.

SPECIFICATION

Dimension & Weight	L 67.5 mm (2.63") x W 38mm (1.48") x H 25mm (0.98"); Without battery < 26g (0.92 ounces)
Display	Full color OLED display
Auto on/off	When a finger is inserted, urns on automatically; vise verso, the device turns off , when the finger is removed.
Input Key	A 5-directional key for screen rotate and device setting.
Measurement Method	Dual wavelength LED (660 nanometers @0.8mW and 940 nanometers @1.2mW; both as max average)
SpO2 Range & Resolution	Range: 0% to 100%; Resolution: 1%
SpO2 Accuracy	Range70%to100%±2%; less than 70% unspecified
Pulse Rate Range&Resolution	Range: 30 to 250bpm; resolution: 1bpm
Pulse Rate Accuracy	±1bpm or ±1%, whichever is greater
Alarm Range	High SpO2 alarm: default off; range: 80%~100%; Low SpO2 alarm: default 87%; range: 50%~95%; High heart rate alarm: default off; range: 75BPM~250BPM Low heart rate alarm: default off; range: 30BPM~110BPM;
Data Storage	Store SpO2 and pulse rate reading with corresponding date and time for up to 960 sets of data (8 hours to 3.5 days)
USB Port (POE101B only)	USB2.0 with Micro USB connector
Water-resistance	Against water splash (IPX2 Approved)
Battery Type	1 AAA size alkaline battery
Usage life	>24 hrs typical operation under default setting
Ambient Temperature	Operating: 5ºCto40ºC (41ºFto104ºF); Storage: -30ºCto70ºC (-22ºFto158ºF)
Atmospheric Pressure	Operating&storage are both 700 hPa to 1013 hPa
Humidity	Operating&storage are both 10% to 90%, non-condensing
Degree of Electrical Protection	Type BF

This device has been tested under compliance with IEC 60601-1, IEC60601-1-2, IEC80601-2-61 and ISO 10993 requirements.

Symbols and terminology

- %SpO2 - The symbol shows the oxygen saturation in percentage.
- BPM - The pulse rate symbol shows pulse rate in beats per minute.
- Pulse Amplitude - It shows the strength of signal being detected by the oximeter.
- - Battery condition symbol. When is shown, battery is at low voltage.
- 30 - Initial Timer. A timing icon appears at the beginning of each measurement for breath timing.
- - Audio is on. The symbol indicate audio alarm and beating sound option is turned on.
- R - Data recording is on (for POE101B only). Record SpO2 and pulse rate measurement with corresponding date and time.

CLEANING THE OXIMETER

Cleaning is as important as proper use. For surface-cleaning and disinfecting the oximeter, please refer to the following procedures:

- Turn off the oximeter before cleaning.
- Clean through the entire device, include the finger contact spot before use.
- Wipe the surfaces with a soft cloth damped with a mild detergent or isopropyl alcohol solution. If low-level disinfection is required, a cloth damped with 10% bleach / 90% water solution may also be used. Do not use undiluted

bleach or any cleaning solution other than those recommended here, as permanent damage could result.
- It is recommended that the oximeter should be kept in a dry environment anytime. High moisture might affect its lifetime and damage the oximeter.

! CAUTION!

- Do not spray, pour, or spill any liquid on the oximeter, accessories, switches or openings.
- Do not use caustic or abrasive cleaning agents on the oximeter.
- This is a precision medical instrument and must be repaired by qualified personnel from manufacturer only.
- Please follow local governing ordinances and recycling instructions regards disposal or recycling of the device and components.
- Manufacturer will provide at least 3 years product service, after manufacturing.

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